January 12, 2015

PUBLISH

Elisabeth A. Shumaker Clerk of Court

UNITED STATES COURT OF APPEALS

TENTH CIRCUIT

CHARLES F. WARNER, BENJAMIN R. COLE, by and through his next friend ROBERT S. JACKSON, JOHN M. GRANT, and RICHARD E. GLOSSIP,

Plaintiffs - Appellants,

JAMES A. CODDINGTON, CARLOS CUESTA-RODRIGUEZ, NICHOLAS A. DAVIS, RICHARD S. FAIRCHILD, WENDELL A. GRISSOM, MARLON D. HARMON, RAYMOND E. JOHNSON, EMMANUEL A. LITTLEJOHN, JAMES D. PAVATT, KENDRICK A. SIMPSON, KEVIN R. UNDERWOOD, BRENDA A. ANDREW, SHELTON D. JACKSON, PHILLIP D. HANCOCK, JULIUS D. JONES, ALFRED B. MITCHELL, and TREMANE WOOD,

Plaintiffs,

v. No. 14-6244

KEVIN J. GROSS, MICHAEL W. ROACH, STEVE BURRAGE, GENE HAYNES, FRAZIER HENKE, LINDA K. NEAL, EARNEST D. WARE, ROBERT C. PATTON, ANITA K. TRAMMELL, EDWARD EVANS, HUNIT SECTION CHIEF X, and JOHN DOE EXECUTIONERS #1-10,

Defendants - Appellees.

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APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA (D.C. No. 5:14-CV-00665-F)

Submitted on the briefs:

Patti Palmer Ghezzi and Randy A. Bauman, Assistant Federal Public Defenders, Western District of Oklahoma, Oklahoma City, Oklahoma, and Mark Henricksen and Lanita Henricksen, Henricksen & Henricksen, Oklahoma City, Oklahoma, and Dale A. Baich and Robin C. Konrad, Assistant Federal Public Defenders, Phoenix, Arizona, for Plaintiffs-Appellants.

John D. Hadden, Jeb E. Joseph, and Aaron J. Stewart, Assistant Attorneys General, Oklahoma Attorney General's Office, Oklahoma City, Oklahoma, for Defendants-Appellees.

Before BRISCOE , C	Chief Judge, GORSUCH and MATHESON, Circ	uit Judges.
BRISCOE, Chief Jud	dge.	

Plaintiffs Charles Warner, Richard Glossip, John Grant, and Benjamin Cole, all Oklahoma state prisoners convicted of first-degree murder and sentenced to death, were among a group of twenty-one Oklahoma death-row inmates who filed this 42 U.S.C. § 1983 lawsuit challenging the constitutionality of the State of Oklahoma's lethal injection protocol. Plaintiffs, facing imminent execution, sought a preliminary injunction to prevent their executions until the district court could rule on the merits of their claims. The district court denied their request. Plaintiffs now appeal. Exercising jurisdiction pursuant to 28 U.S.C. § 1292(a)(1), we agree with the district court that plaintiffs have

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failed to establish a likelihood of success on the merits of their claims. We therefore affirm the decision of the district court.¹

I

The Plaintiffs

In August 1997, plaintiff Charles Warner anally raped and murdered the elevenmonth-old daughter of his girlfriend. Warner was subsequently convicted by a jury of first degree rape and first degree murder. Warner v. State, 144 P.3d 838, 856 (Okla. Crim. App. 2006). Warner was sentenced, in accordance with the jury's recommendation, to death for the murder conviction. Id.

In January 1997, plaintiff Richard Glossip, who at the time was working as the manager of an Oklahoma City motel, hired another motel employee, Justin Sneed, to kill the owner of the motel. Per Glossip's suggestion, Sneed carried out the murder by beating the owner to death with a baseball bat. Glossip was ultimately convicted by a jury of first degree malice murder and sentenced to death for that conviction. Glossip v. State, 157 P.3d 143, 147 (Okla. Crim. App. 2007).

In November 1998, plaintiff John Grant, at the time a prisoner at the Conner Correction Center in Hominy, Oklahoma, murdered a food service supervisor by repeatedly stabbing her with a prison-made shank. Grant was convicted by a jury of first

¹ After examining the brief and appellate record, this panel has determined unanimously that oral argument would not materially assist in the determination of this appeal. See Fed. R. App. P. 34(a)(2); 10th Cir. R. 34.1(G). The case is, therefore, submitted without oral argument.

degree malice murder and sentenced to death. <u>Grant v. State</u>, 58 P.3d 783, 788 (Okla. Crim. App. 2002).

In December 2002, plaintiff Benjamin Cole murdered his nine-month-old daughter by pushing her legs towards her head as she lay on her stomach crying. Cole's actions snapped his daughter's spine in half and resulted in a complete tear of her aorta. Cole was subsequently convicted by a jury of first degree murder and sentenced to death. Cole v. State, 164 P.3d 1089, 1092 (Okla. Crim. App. 2007).

All four of the plaintiffs have exhausted their state and federal court remedies and the State of Oklahoma has established specific execution dates for each of them. Plaintiff Warner is scheduled to be executed on January 15, 2015. Plaintiff Glossip is scheduled to be executed on January 29, 2015. Plaintiff Grant is scheduled to be executed on February 19, 2015. Plaintiff Cole is scheduled to be executed on March 5, 2015.

The State's Lethal Injection Protocol

For many years, the State of Oklahoma utilized a three-drug lethal injection protocol comprised of sodium thiopental, pancuronium bromide, and potassium chloride. "The first drug, sodium thiopental . . . , is a fast-acting barbiturate sedative that induces a deep, comalike unconsciousness when given in the amounts used for lethal injection." <u>Baze v. Rees</u>, 533 U.S. 35, 44 (2008). "The second drug, pancuronium bromide . . . , is a paralytic agent that inhibits all muscular-skeletal movements and, by paralyzing the

diaphragm, stops respiration." Id. "Potassium chloride, the third drug, interferes with the electrical signals that stimulate the contractions of the heart, inducing cardiac arrest." Id.

Since approximately 2010, the State of Oklahoma has been unable to obtain sodium thiopental, either commercially manufactured or compounded, for use in executions. Although the State of Oklahoma was able, for a short time, to obtain and utilize an alternative barbiturate, pentobarbital, during executions, that drug has also become unavailable to the State of Oklahoma for use in its executions. See Pavatt v. Jones, 627 F.3d 1336, 1337 (10th Cir. 2010) (addressing challenge to State of Oklahoma's planned use of pentobarbital).

In approximately early 2014, the State of Oklahoma decided to substitute midazolam hydrochloride (midazolam), a sedative in the benzodiazepine family of drugs, for sodium thiopental and pentobarbital. In other words, the State of Oklahoma intended for midazolam to be utilized, as the first drug in its lethal injection protocol, to render an inmate unconscious prior to the injection of the second and third drugs.

The Clayton Lockett Execution

On April 29, 2014, inmate Clayton Lockett was the first Oklahoma state prisoner to be executed using midazolam as part of the lethal injection execution protocol. As

² In recent years, the State of Oklahoma has substituted vecuronium bromide for pancuronium bromide. And, for the executions of the four plaintiffs in this appeal, the State of Oklahoma has expressed its intent to substitute rocuronium bromide for vecuronium bromide. These substitutions are not at issue in this appeal.

described at length in the district court's oral ruling, Lockett's execution, though ultimately successful, was a procedural disaster. The execution team, over the course of nearly an hour, made at least twelve attempts to establish intravenous (IV) access to Lockett's cardiovascular system. The team ultimately believed, incorrectly, that they had successfully established IV access through Lockett's right femoral vein. And the team compounded this error by placing a hemostat on the IV line and covering the IV injection access point with a sheet.

The execution team proceeded to inject Lockett with the three-drug protocol. In doing so, the team declared Lockett to be unconscious following the injection of the midazolam and prior to the injection of the vecuronium bromide and the potassium chloride. Shortly after the injection of part, but not all, of the potassium chloride, however, Lockett began to move and speak. In particular, witnesses heard Lockett say: "This shit is fucking with my mind," "something is wrong," and "The drugs aren't working." ROA, Vol. 3 at 865.

The execution team lifted the sheet and observed a large area of swelling, smaller than a tennis ball but larger than a golf ball, near the IV access point. The execution team determined that the IV had infiltrated, meaning that the IV fluid, rather than entering Lockett's blood stream, had leaked into the tissue surrounding the IV access point. The team stopped administration of the remaining potassium chloride and attempted, unsuccessfully, to insert the IV into Lockett's left femoral vein.

The execution team, after concluding that Lockett had no viable veins left in which

to obtain IV access, terminated the execution process approximately 33 minutes after the midazolam was first injected into Lockett. Approximately ten minutes later, Lockett was pronounced dead, even though the execution team had not injected the intended amount of potassium chloride into Lockett.

A subsequent autopsy determined that there was a concentration of midazolam in the tissue near the IV insertion site in Lockett's right groin area. The autopsy also determined, however, that certain amounts of all three drugs had been distributed throughout Lockett's body, and that the concentration of midazolam in Lockett's blood was greater than the concentration required to render an average person unconscious.

Oklahoma's Revised Execution Procedures

After conducting an investigation into Lockett's execution, the State of Oklahoma adopted a new execution protocol, effective September 30, 2014. As the district court found, the new protocol "is noticeably more detailed" in terms of the "procedures for establishing IV access to the offender's cardiovascular system, the procedure for administering the chemicals, and the procedures for dealing with mishaps or unexpected contingencies." <u>Id.</u> at 870. In particular, "[t]ne new protocol provides for the insertion of a primary IV catheter and a backup IV catheter," <u>id.</u> at 875, and allows for an execution to be postponed if viable IV sites cannot be established within an hour's time, <u>id.</u> at 876. The new protocol "also includes detailed provisions with respect to training and pre-execution preparation of the members of the execution team." <u>Id.</u> at 870.

The new protocol gives the Director of Oklahoma's Department of Corrections

(DOC) "four alternatives with respect to the combination of drugs to be used in the lethal injection process." Id. at 874. The first alternative "calls for the administration of 5,000 milligrams of pentobarbital in a one-drug procedure." Id. The second alternative "provides for the administration of 5,000 milligrams of sodium pentothal . . . in a one-drug procedure." Id. The third alternative "provides for the administration of 500 milligrams of midazolam and 500 milligrams of hydromorphone." Id. The fourth alternative "provides for the administration of 500 milligrams of midazolam, 100 milligrams of vecoronium bromide, and 240 milliequivalents of potassium chloride." Id. Under the new protocol, the Director "shall have the sole discretion to determine which chemicals will be used for the scheduled execution." Id. "This decision is required to be provided to the offender in writing ten calendar days before the scheduled execution date." Id.

It is undisputed that the Director has selected the fourth alternative, i.e., the midazolam/vecoronium bromide/potassium chloride combination, for use in the executions of the four plaintiffs in this case and has notified plaintiffs of that fact.³

Π

Plaintiffs' Complaint

On June 25, 2014, the four plaintiffs, along with seventeen other Oklahoma inmates sentenced to death, initiated this action by filing a 42 U.S.C. § 1983 complaint

³ In their appellate brief, defendants acknowledge that they "only ha[ve] immediate plans to use" the fourth alternative in carrying out lethal injections. Aplee. Br. at 12.

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against the Director and various other DOC officials. The complaint alleged eight counts.

Of relevance to this appeal are Counts 2 and 7.

Count 2 challenges, as violative of the Eighth Amendment, the defendants' proposed use of midazolam in Oklahoma's lethal injection protocol. In support, Count 2 alleges that the inherent characteristics of midazolam—including an alleged ceiling effect (i.e., a certain dosage level beyond which incremental increases in dosage would have no corresponding incremental effect) and an alleged risk of paradoxical reactions (such as agitation, involuntary movements, hyperactivity, and combativeness)—render it unsuitable "as a stand-alone anesthetic," ROA, Vol. 1 at 960, and thus poses a substantial risk that an inmate would experience "severe pain, needless suffering, and a lingering death," <u>id.</u> at 963. In addition, the plaintiffs allege as part of Count 2 that there is a substantial risk that midazolam will, as exemplified by the Lockett execution, be negligently administered and thus result in an inmate consciously experiencing the painful effects of the second and third drugs utilized in the execution protocol.

Count 7, entitled "Eighth Amendment - Experimentation on Captive Human Subjects," alleges that defendants, "[b]y attempting to conduct executions with an everchanging array of untried drugs of unknown provenance, using untested procedures, . . . are engaging in a program of biological experimentation on captive and unwilling human subjects." <u>Id.</u> at 979. Count 7 further alleges that there is no "scientifically sound expectation that these experiments will succeed in producing an execution that does not inflict severe pain, needless suffering, or a lingering death." Id. According to Count 7,

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the defendants "have acted and will act with deliberate indifference to the [se] [identified] risks," and that "[if] the attempted executions of the Plaintiffs are allowed to proceed, the Plaintiffs . . . will be subjected to cruel and unusual punishment." Id. at 980.

Plaintiffs' Motion for Preliminary Injunction

On November 10, 2014, the four plaintiffs in this appeal filed a motion for preliminary injunction. The motion asked the district court to "maintain the status quo by barring Defendants from implementing" the new protocol and executing the four plaintiffs "until this litigation is complete and th[e] Court has had a chance to rule on the merits." <u>Id.</u> at 1082. In support, the four plaintiffs alleged, in pertinent part, that they could demonstrate a likelihood of success on Counts 2 and 7 of their complaint.⁴

In December 2014, the district court held a three-day evidentiary hearing on plaintiffs' motion. Plaintiffs presented testimony from ten lay witnesses and four expert witnesses and submitted numerous exhibits. Defendants presented testimony from one expert witness, a DOC official who oversaw the investigation into the Lockett execution, and the medical examiner who performed an autopsy on Lockett's body.

The District Court's Ruling on Plaintiffs' Motion

On December 22, 2014, the district court ruled from the bench and denied plaintiffs' motion for preliminary injunction. In doing so, the district court concluded that plaintiffs failed to establish a likelihood of success on the merits of Counts 2 or 7. The

⁴ The motion also alleged a likelihood of success on the merits of Counts 4, 5 and 6 of the complaint. Those counts are not, however, at issue in this appeal.

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district court also concluded that plaintiffs "failed to establish any of the [other] prerequisites to a grant of preliminary injunctive relief." ROA, Vol. 3 at 930.

Plaintiffs filed a notice of appeal on December 23, 2014. They have since filed an emergency motion for stay of execution pursuant to Federal Rules of Appellate Procedure 8 and 27.

III

We review a district court's decision to deny a preliminary injunction under a deferential abuse of discretion standard. <u>Citizens United v. Gessler</u>, — F.3d —, 2014 WL 6685443 *8 (10th Cir. Nov. 12, 2014). "Under this standard, we examine the district court's legal determinations de novo, and its underlying factual findings for clear error." <u>Id.</u> (internal quotation marks omitted). Thus, we will find an abuse of discretion if the district court denied the preliminary injunction on the basis of a clearly erroneous factual finding or an error of law. <u>Id.</u>

"A preliminary injunction is an 'extraordinary and drastic remedy." Munaf v. Geren, 553 U.S. 674, 689 (2008) (quoting 11A C. Wright, A. Miller, & M. Kane, Federal Practice and Procedure § 2948, p. 129 (2d ed. 1995)). "A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." Winter v. Natural Res.

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Def. Council, Inc., 555 U.S. 7, 20 (2008).5

A motion for stay pending appeal is subject to the exact same standards. In other words, "[i]n ruling on such a request, this court makes the same inquiry as it would when reviewing a district court's grant or denial of a preliminary injunction." Homans v. City of Albuquerque, 264 F.3d 1240, 1243 (10th Cir. 2001).

A. Plaintiffs' likelihood of success on the merits of Counts 2 and 7

The district court in this case grounded its denial of plaintiffs' motion for preliminary injunction, in large measure, on its conclusion that plaintiffs failed to establish a likelihood of success on the merits of Counts 2 and 7. On appeal, plaintiffs assert a number of challenges to that conclusion. In addressing those challenges, we begin by outlining the general principles applicable to Counts 2 and 7. We then review the precise basis for the district court's conclusion that plaintiffs failed to establish a likelihood of success on these two counts. Lastly, we shall explain why, in our view, plaintiffs' challenges to the district court's decision lack merit.

⁵ Plaintiffs argue on appeal that they need only "raise[] questions going to the merits [of Counts 2 and 7] so serious, substantial, difficult and doubtful, as to make them a fair ground for litigation." Aplt. Br. at 33 (quoting <u>Kikumura v. Hurley</u>, 242 F.3d 950, 955 (10th Cir. 2001)). We are not persuaded, however, that this relaxed standard is consistent with Supreme Court precedent. Indeed, in <u>Hill v. McDonough</u>, 547 U.S. 573, 584 (2006), the Supreme Court emphasized that "inmates seeking time to challenge the manner in which the State plans to execute them must," in pertinent part, establish "a significant possibility of success on the merits."

In any event, we are not persuaded, based upon our review of the record on appeal, that plaintiffs can satisfy the relaxed standard that they urge us to adopt.

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1. Applicable constitutional principles

This is far from the first constitutional challenge mounted to a State's proposed method of execution. Consequently, we have several related and well-established principles upon which we can rely. The first is that capital punishment itself has been held not to violate the Eighth Amendment's prohibition against the infliction of cruel and unusual punishments. Baze, 553 U.S. at 47. Second, the Supreme Court "has never invalidated a State's chosen procedure for carrying out a sentence of death as the infliction of cruel and unusual punishment." <u>Id.</u> at 48. Third, the Court has recognized "that there must be a means of carrying . . . out" capital punishment and that "[s]ome risk of pain is inherent in any method of execution—no matter how humane—if only from the prospect of error in following the required procedure." Id. at 47. Thus, the Court has emphasized, "the Constitution does not demand the avoidance of all risk of pain in carrying out executions." <u>Id.</u> More specifically, "because an execution method may result in pain, either by accident or as an inescapable consequence of death, does not establish the sort of 'objectively intolerable risk of harm' that qualifies as cruel and unusual." Id.

All of this said, it remains true "that subjecting individuals to a risk of future harm—not simply actually inflicting pain—can qualify as cruel and unusual punishment." <u>Id.</u> at 49. "To establish that such exposure violates the Eighth Amendment, however, the conditions presenting the risk must be 'sure or very likely to cause serious illness and

needless suffering,' and give rise to 'sufficiently *imminent* dangers.'" Id. at 49-50 (quoting Helling v. McKinney, 509 U.S. 25, 33, 34-35 (1993)) (emphasis added in Baze). In other words, "there must be a 'substantial risk of serious harm,' an 'objectively intolerable risk of harm' that prevents prison officials from pleading that they were 'subjectively blameless for purposes of the Eighth Amendment." Id. (quoting Farmer v. Brennan, 511 U.S. 825, 842, 846, and n.9 (1994)). Finally, the Supreme Court has stated that "[a] stay of execution may not be granted" on the basis of an Eighth Amendment challenge to a State's lethal injection protocol "unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain" and "that the risk is substantial when compared to the known and available alternatives." Id. at 61.

2. The district court's assessment of Counts 2 and 7

With these principles in mind, we turn to Counts 2 and 7 of plaintiffs' complaint and the district court's analysis of them. Count 2 alleges, in essence, that the use of midazolam during a lethal injection procedure presents a substantial risk of serious harm both because of the inherent characteristics of midazolam, including most notably its alleged ceiling effect and its alleged risk of paradoxical reactions, and because of the

⁶ These key holdings are found in Chief Justice Roberts' plurality opinion in <u>Baze</u>. Although that opinion was joined by only three Justices, it represents the "narrowest grounds" for the judgment in the case, and thus contains the holdings of the Court. <u>Marks v. United States</u>, 430 U.S. 188, 193 (1977); <u>see Chavez v. Florida SP Warden</u>, 742 F.3d 1267, 1271-1272 n.4 (11th Cir. 2014) (reaching same conclusion); <u>Dickens v. Brewer</u>, 631 F.3d 1193, 1145-1146 (9th Cir. 2011) (same); <u>Jackson v. Danberg</u>, 594 F.3d 210, 222-223 (3d Cir. 2010) (same).

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likelihood that it will be negligently administered by prison officials. Count 7 effectively alleges that defendants, by adopting a revised lethal injection protocol that includes a new drug, i.e., midazolam, and new procedures, lack any reasonable expectation that the revised protocol and procedures will avoid the infliction of severe pain, needless suffering, or a lingering death. And both counts alleged that "[i]t would be feasible" for defendants "to use sodium thiopental in a single-drug formulation to" carry out the executions, ROA, Vol. 1 at 946, and that the use of sodium thiopental "would significantly reduce the substantial risk of severe pain posed by" midazolam, <u>id.</u> at 946-947.

In addressing plaintiffs' likelihood of success on these allegations, the district court found that "[t]he 500 milligram dosage of midazolam, as called for in . . . the revised protocol, is many times higher than a normal therapeutic dose of midazolam" and "will result in central nervous system depression as well as respiratory arrest and cardiac arrest." ROA, Vol. 3 at 892. The district court further found that a 500 milligram dosage of midazolam "is highly likely to render the person unconscious and insensate during the remainder of the procedure" and that, "[c]onsequently, analgesia, from midazolam or otherwise, is not necessary." Id. at 892-893. In sum, the district court found that "[t]he proper administration of 500 milligrams of midazolam . . . would make it a virtual certainty that an individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur from application of the second and third drugs" called for by the revised protocol, and that "a 500 milligram dose [of midazolam] alone would

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be likely to cause death by respiratory arrest within an hour and probably closer to 30

minutes." Id. at 893.

The district court, relatedly, made factual findings relevant to plaintiffs' claims that midazolam has a ceiling effect and a risk of paradoxical reactions, either of which, according to plaintiffs, could result in an inmate consciously experiencing the effects of the second and third drugs in the revised protocol. With respect to the purported ceiling effect, the district court expressly found "persuasive[]" the testimony of defendants' expert witness, Dr. Roswell Lee Evans, the Dean of the School of Pharmacy at Auburn University. Id. at 894. As summarized by the district court, Dr. Evans testified that "whatever the ceiling effect of midazolam may be with respect to anesthesia, which takes effect at the spinal cord level, there is no ceiling effect with respect to the ability of a 500 milligram dose of midazolam to effectively paralyze the brain." Id. This "phenomenon," according to Dr. Evans, "is not anesthesia but does have the effect of shutting down respiration and eliminating the individual's awareness of pain." Id. Thus, the district court essentially rejected plaintiffs' allegation that the 500 milligram dose of midazolam called for in the revised protocol carries a substantial risk

The district court likewise found Dr. Evans' testimony persuasive with respect to the risk of a paradoxical reaction. In particular, the district court found "that with a low therapeutic dose of midazolam there would be less than a 1 percent incidence of a paradoxical reaction." <u>Id.</u> at 895. The district court in turn found that "[n]o data [was] available to show what . . . the likelihood of a paradoxical reaction would be with a 500

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milligram IV dose of midazolam." <u>Id.</u> Thus, the district court found that risk "speculative" at best. <u>Id.</u>

As for the likelihood of negligent administration of midazolam, the district court "conclude[d], as a matter of law, that the revised lethal injection protocol adopted by [defendants] is facially constitutional when measured by the principles promulgated in <u>Baze"</u>." <u>Id.</u> at 916 (emphasis added). In doing so, the district court "place[d] considerable reliance... on three aspects of the [revised] lethal injection protocol." <u>Id.</u> at 917. These included "the requirement that both primary and backup IV access sites be established," "that confirmation of the viability of the IV sites is specifically required," and "that the offender's level of consciousness must be monitored throughout the procedure." <u>Id.</u> The district court in turn "conclude[d] on the basis of the evidence before [it] that plaintiffs ha[d] failed to establish that proceeding with the[ir] execution[s]... on the basis of the revised protocol present[ed] a risk that is 'sure or very likely to cause serious illness and needless suffering,' amounting to 'an objectively intolerable risk of harm." Id. at 916.

As for plaintiffs' allegation that "[i]t would be feasible to use sodium thiopental in a single-drug formulation to" carry out their executions, ROA, Vol. 1 at 946, the district court found this allegation groundless. In particular, the district court noted that "the defendants have affirmatively shown that sodium thiopental and pentobarbital . . . are not available to the DOC." ROA, Vol. 3 at 918. The district court also noted that the defendants' evidence was consistent with the finding in <u>Pavatt</u> that "sodium thiopental is now effectively unobtainable anywhere in the United States, thus requiring Oklahoma and

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other death-penalty states to revise their lethal injection protocols." 627 F.3d at 1338 n.1

As for the allegations of Count 7, the district court found that "[a]s a factual matter, by plaintiffs' own count, execution with midazolam as part of a three-drugprotocol has been accomplished [nationwide] 12 times." ROA, Vol. 3 at 926. Consequently, the district court found "[t]his is not a new method, at least in the sense required for the Court to regard its use as human experimentation." Id. The district court also concluded, as a matter of law, that the plaintiffs failed to "establish that the state's lethal injection protocol creates a demonstrated risk of severe pain and that the risk is substantial when compared to the known and available alternatives." Id. at 927.

3. The plaintiffs' challenges to the district court's analysis

In their appeal, plaintiffs mount several challenges to the district court's analysis.⁷ As we explain in greater detail below, we conclude that all of these challenges lack merit.

a. The district court's application of <u>Baze</u>

According to plaintiffs, "[t]he district court misapplied Baze in four key ways." Aplt. Br. at 37. First, they argue, the district court "decided that [plaintiffs] could not succeed because they failed to present an alternative remedy." Id. "Second," plaintiffs argue, the district court "improperly assumed that the grounds asserted in this case were similar to those asserted in Baze, therefore skewing the court's risk assessment." Id. "Third," plaintiffs argue, the district court "determined that any potential risk was cured

⁷ We note that plaintiffs are not appealing the district court's decision regarding the negligent administration portion of Count 2.

by three factors built into the [revised] protocol." <u>Id.</u> Lastly, plaintiffs argue that the district court "failed to consider evolving standards of decency in its analysis." <u>Id.</u>

The first three of these arguments derive from the undisputed fact that the plaintiffs in this case, unlike the petitioners in <u>Baze</u>, are challenging the inherent characteristics of a drug proposed to be used as part of their lethal injection protocol. In <u>Baze</u>, the petitioners asserted only a "risk that the [lethal injection] protocol's terms might not be properly followed" and, to remedy that concern, they "propose[d] an alternative protocol." 553 U.S. at 41. The petitioners in <u>Baze</u> conceded that the drugs proposed to be used in their executions, if properly administered, would "result in a humane death." <u>Id.</u>

As we have already noted, the Supreme Court in <u>Baze</u> held, in addressing the petitioners' claims, that "[a] stay of execution may not be granted on grounds such as those asserted here unless the condemned prisoner establishes that the State's lethal injection protocol creates a demonstrated risk of severe pain." <u>Id.</u> at 61. And, the Court further held, "[h]e must show that the risk is substantial when compared to the known and available alternatives." <u>Id.</u> Although plaintiffs assert that this latter requirement, i.e., proof of "known and available alternatives," is inapplicable when the challenge at issue concerns the inherent characteristics of a drug proposed to be used as part of the lethal injection protocol, this court previously decided otherwise in <u>Pavatt</u>. Like the plaintiffs in this case, the plaintiff in <u>Pavatt</u> asserted an Eighth Amendment challenge to a

⁸ Curiously, plaintiffs make no mention of <u>Pavatt</u> in either of their appellate briefs.

replacement drug (pentobarbital) proposed to be used as part of his lethal injection protocol. Specifically, the plaintiff's expert witness in Pavatt "expressed concern that there was insufficient data to allow [the State of Oklahoma] to determine the proper amount of pentobarbital to use as part of its protocol." 627 F.3d at 1340. In addressing this claim, both the district court and this court in Pavatt relied on the principles outlined in Baze. In particular, this court expressly noted that, to obtain a stay of execution, the plaintiff would have to establish "that the risk is substantial when compared to the known and available alternatives." Id. at 1339 (quoting Baze, 553 U.S. at 61). Quite clearly, we are bound by Pavatt, "absent superseding en banc review or Supreme Court decisions." Rezaq v. Nalley, 677 F.3d 1001, 1012 n.5 (10th Cir. 2012). And, as the district court noted, plaintiffs have not identified any known and available alternatives.

In any event, this second <u>Baze</u> requirement is not outcome-determinative in this case because the plaintiffs have failed to establish that the use of midazolam in their executions, either because of its inherent characteristics or its possible negligent administration, creates a demonstrated risk of severe pain. In other words, it is not even necessary in this case to "reach the second step of the <u>Baze</u> test." <u>Raby v. Livingston</u>,

⁹ Even if we were free to decide the issue in the first instance, we would agree with the Eighth Circuit that, even in the context of a challenge to a particular drug proposed to be used as part of a lethal injection protocol, <u>Baze</u> requires the plaintiff to establish, in part, the existence of a "known and available alternative." <u>See In re Lombardi</u>, 741 F.3d 888, 895-896 (8th Cir. 2014) (concluding, in the context of a challenge to the proposed use of compounded pentobarbital, that <u>Baze</u> required the plaintiffs, in the absence of proof that the State purposefully intended to inflict unnecessary pain, to demonstrate a feasible and more humane alternative method of execution).

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600 F.3d 552, 560 (5th Cir. 2010).

To the extent that plaintiffs are asserting that the differences in claims renders inapplicable <u>Baze</u>'s other holdings, including its first requirement for a stay of execution (i.e., the demonstration of a risk of severe pain), we disagree. The constitutional principles announced in <u>Baze</u>, as we read them, were not confined to claims of negligent administration of lethal injection protocols. Rather, they were intended to apply to all challenges to "a State's chosen procedure for carrying out a sentence of death," 553 U.S. at 48. Thus, we conclude that the district court did not err in applying those principles in assessing plaintiffs' likelihood of success on the merits of Counts 2 and 7.

As for the plaintiffs' third argument, we see no error on the part of the district court in relying on three aspects of the revised lethal injection protocol (i.e., the requirement that both primary and backup IV sites be established, the requirement that the viability of these IV sites are confirmed prior to administration of any drugs, and the requirement that the inmate's level of consciousness be monitored throughout the entire execution procedure). As the district court's oral ruling makes clear, this reliance was not relevant to its rejection of plaintiffs' claims regarding the inherent characteristics of midazolam, but rather to its rejection of plaintiffs' claim of negligent administration. In any event, we see nothing in this aspect of the district court's ruling that is contrary to, or a misapplication of, <u>Baze</u>.

That leaves only plaintiffs' argument that the district court violated <u>Baze</u> by "fail[ing] to consider evolving standards of decency in its analysis." Aplt. Br. at 37. In

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support, plaintiffs complain that "Florida is the only other state that has carried out executions using a three-drug protocol with midazolam as the first drug," <u>id.</u> at 44, "there have been reports of prisoner movement in Florida," <u>id.</u> at 45, and that these facts alone render the defendants' revised lethal injection protocol "objectively intolerable," <u>id.</u>

Nothing in <u>Baze</u>, however, supports these arguments. To be sure, the protocol at issue in <u>Baze</u> enjoyed widespread use at the time of the Supreme Court's decision. But that fact was not critical to, nor was it made a part of, the Supreme Court's key holdings in <u>Baze</u>. Indeed, if that were a requirement, it would effectively prevent any state from revising its execution protocol.

b. The district court's reliance on Dr. Evans' testimony

Plaintiffs next argue that the district court abused its discretion by relying on Dr. Evans' testimony and that, in turn, the district court's factual findings that were based on Dr. Evans' testimony were clearly erroneous. We address these arguments in turn.

Plaintiffs begin by asserting that "the district court abused its discretion in relying on Dr. Evans' testimony at all because his opinions are unsupported ipse dixit . . . and based on fundamental errors in his analysis." Aplt. Br. at 46. "Federal Rule of Evidence 702 requires a district court to assess proffered expert testimony to ensure it is both relevant and reliable." <u>United States v. Avitia-Guillen</u>, 680 F.3d 1253, 1256 (10th Cir. 2012) (citing <u>Daubert v. Merrell Dow Pharms., Inc.</u>, 509 U.S. 579, 589 (1993) (scientific knowledge); <u>Kumho Tire Co., Ltd. v. Carmichael</u>, 526 U.S. 137, 141 (1999) (technical and other specialized knowledge)). A district court "generally must first determine

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whether the expert is qualified by knowledge, skill, experience, training, or education to render an opinion." <u>Id.</u> (internal quotation marks omitted). "If the expert is sufficiently qualified, then the court must determine whether the expert's opinion is reliable by assessing the underlying reasoning and methodology." <u>Id.</u> (internal quotation marks omitted). "Although a district court has discretion in how it performs its gatekeeping function, when faced with a party's objection, the court must adequately demonstrate by specific findings on the record that it has performed its duty as gatekeeper." <u>Id.</u> (internal quotation marks and brackets omitted).

Generally speaking, we review de novo whether the district court actually performed its gatekeeper role in the first instance and whether it applied the proper standard in admitting expert testimony. <u>Id.</u> And, in turn, if the district court performed its gatekeeper role and applied the proper legal standard, we then review for abuse of discretion the district court's decision to admit or exclude the testimony. <u>Id.</u> Under this abuse of discretion standard, we will "reverse only if the district court's conclusion is arbitrary, capricious, whimsical or manifestly unreasonable or when we are convinced that the district court made a clear error of judgment or exceeded the bounds of permissible choice in the circumstances." <u>Id.</u> (internal quotation marks omitted).

In this case, there is no question that the district court actually performed its gatekeeper role and applied the proper standards in doing so. During its oral ruling on plaintiffs' motion for preliminary injunction, the district court expressly noted that "Daubert . . . and Kumho . . . establish a gatekeeper function for trial judges under Rule

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702 of the Federal Rules of Evidence." ROA, Vol. 3 at 886 (emphasis added). The district court in turn, noting that plaintiffs were challenging "both Dr. Evans' qualifications and his methodology," id. at 887, proceeded to outline in detail the <u>Daubert</u> and <u>Kumho</u> standards, <u>id.</u> at 886-889. In our view, the district court considered and applied the correct standards.

We are thus left to determine whether the district court abused its discretion in admitting and in turn relying on Dr. Evans' testimony. As a threshold matter, the district court "reject[ed] plaintiffs' challenge to Dr. Evans' qualifications," noting that "[h]is qualifications go far beyond those of an everyday pharmacist and his clinical experience is an obvious adjunct of his academic attainments." <u>Id.</u> at 890. After reviewing Dr. Evans' curriculum vitae and testimony, we conclude that the district court did not abuse its discretion in so ruling. Dr. Evans is the Dean of the Auburn University Harris School of Pharmacy and holds a Pharm.D. from the University of Tennessee. Dr. Evans' academic experience is extensive, having taught as a professor at three different universities over the course of approximately forty years. Dr. Evans has also worked in a variety of clinical pharmacy settings. As the district court aptly noted, Dr. Evans' qualifications are "considerable." <u>Id.</u>

The district court then evaluated the reliability of "Dr. Evans' testimony . . . with respect to the risk that a 500 milligram dose of midazolam will fail to induce a state of unconsciousness and his criticisms of the [plaintiffs'] contentions that there is a ceiling effect that is relevant to the determination of whether the prisoner will experience pain

after IV administration of 500 milligrams of midazolam." <u>Id.</u> at 891. The district court concluded that this "testimony was the product of reliable principles and methods reliably applied to the facts of this case." <u>Id.</u> Although plaintiffs point to what they perceive as a number of errors in Dr. Evans' testimony, we conclude these errors were not sufficiently serious to render unreliable Dr. Evans' testimony regarding the likely effect of a 500 milligram dose of midazolam, or to persuade us that the district court's decision to admit Dr. Evans' testimony amounted to an abuse of discretion. Moreover, we note that plaintiffs do not argue that the district court failed to make adequate <u>Daubert</u> findings regarding Dr. Evan's testimony.

That leaves only the plaintiffs' challenge to the district court's factual findings regarding midazolam. After admitting Dr. Evans' testimony, the district court relied on that testimony to make a series of factual findings. To begin with, the district court found that "[t]he 500 milligram dosage of midazolam . . . is many times higher than a normal therapeutic dose of midazolam" and "will result in central nervous system depression as well as respiratory arrest and cardiac [ar]rest." Id. at 892. In turn, the district court found that a 500 milligram dosage of midazolam "is highly likely to render the person unconscious and insensate during the remainder of the [lethal injection] procedure" and that, "[c]onsequently, analgesia, from midazolam or otherwise, is not necessary." Id. at 893-893. In sum, the district court found that "[t]he proper administration of 500 milligrams of midazolam . . . would make it a virtual certainty that any individual will be at a sufficient level of unconsciousness to resist the noxious stimuli which could occur . . .

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from the administration of the second and third drugs . . . , assuming that proper intravenous access has been established." <u>Id.</u> at 893. The district court also found that, "because midazolam is water soluble" and "crosses the blood brain barrier very quickly," "[t]he administration of a 500 milligram dose alone would be likely to cause death by respiratory arrest within an hour and probably closer to 30 minutes." <u>Id.</u>

The district court also relied on Dr. Evans' testimony to rebut plaintiffs' claims that midazolam has both a ceiling effect and a risk of paradoxical effects. With respect to the alleged ceiling effect, the district court found that "Dr. Evans testified persuasively, in substance, that whatever the ceiling effect of midazolam may be with respect to anesthesia, which takes effect at the spinal cord level, there is no ceiling effect with respect to the ability of a 500 milligram dose of midazolam to effectively paralyze the brain, a phenomenon which is not anesthesia but does have the effect of shutting down the individual's awareness of pain." <u>Id.</u> at 894. In addition, the district court found that "[t]he dosage at which the ceiling effect may occur at the spinal cord level is unknown because no testing to ascertain the level at which the ceiling effect occurs has been documented." Id. As for paradoxical effects, the district court acknowledged that, according to midazolam's product label, "[t]he use of midazolam presents a risk of paradoxical reactions or side effects such as agitation, involuntary movements, hyperactivity, and combativeness." <u>Id.</u> at 894-895. The district court found that "[t]he likelihood that a paradoxical reaction will occur in any particular instance is speculative, but . . . occurs with the highest frequency in low therapeutic doses." Id. at 895. Even

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then, the district court found, "there would be less than a 1 percent incidence of a paradoxical reaction." Id. And, the district court noted, "[n]o data are available to show what . . . the likelihood of a paradoxical reaction would be with a 500 milligram IV dose of midazolam." Id. Ultimately, the district court found that "[t]he evidence falls well short of establishing that the risk of a paradoxical reaction at a 500 milligram IV dosage presents anything more than a mere possibility in any given instance that midazolam will fail to deliver its intended effect." Id.

After carefully examining the record on appeal, we are unable to say that any of these factual findings are clearly erroneous. To be sure, plaintiffs' counsel, in crossexamining Dr. Evans, focused on what appear to have been certain errors in his testimony. These include Dr. Evans' misidentification of the reported toxic dose range of midazolam (i.e., the dose range at which deaths have actually occurred from midazolam in a clinical setting), his assertion that Material Safety Data Sheets are mandated by the Federal Drug Administration rather than the Occupational Safety and Health Administration, and his testimony that midazolam inhibits gamma aminobutyric acid (GABA). We are not persuaded, however, that any of this seriously undercuts the key portions of Dr. Evans' testimony that were relied on by the district court. As Dr. Evans noted both in his report and in court, the 500 milligram dose of midazolam called for in defendants' revised lethal injection protocol is at least 100 times the normal therapeutic IV dose and, if properly administered, will render a person unconscious and insensate during the remainder of the lethal injection procedure.

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c. The district court's conclusions regarding Count 7

Plaintiffs contend the district court erred in analyzing Count 7 because it "applied its interpretation of the risk-analysis test in <u>Baze</u>" instead of "applying the 'evolving standards of decency' analysis." Aplt. Br. at 57. We have already considered and rejected a similar, if not identical, argument above. In any event, we reject plaintiffs' assertion that Count 7 is not subject to the principles or mode of analysis outlined in <u>Baze</u>.

d. Summary

We ultimately conclude, having rejected plaintiffs' various challenges to the district court's analysis of Counts 2 and 7, that the district court correctly determined that plaintiffs failed to establish a significant possibility of success on the merits of Counts 2 or 7.

B. The remaining three requirements for preliminary injunction

As part of their appeal, plaintiffs also argue that "[t]he district court erred when it concluded [they] could not demonstrate the other three requirements for a preliminary injunction." Aplt. Br. at 62. Having concluded, however, that plaintiffs failed to establish a significant possibility of success on the merits of Counts 2 or 7, we find it unnecessary to address the remaining requirements for a preliminary injunction.

C. Emergency motion for stay of execution

As we have noted, the standards for granting a motion for a stay pending appeal, or more precisely in this context a stay of the plaintiffs' executions, are identical to those for

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granting a preliminary injunction. Having concluded that plaintiffs failed to establish a significant possibility of success on the merits of Counts 2 or 7, we therefore deny their emergency motion for stay of execution pending appeal.

IV

The district court's order denying a preliminary injunction is AFFIRMED.¹⁰ Plaintiffs' emergency motion for a stay of execution pending appeal is DENIED.

¹⁰ In an abundance of caution, this opinion was circulated to all active judges of this court prior to publication. No judge requested a poll on the questions presented by plaintiffs. Thus, no *en banc* consideration is warranted or available.